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(54) Biological electrical stimulators

(57) Biological stimulators, suitable for relieving various types of pains at a plurality of locations on a living organism, include circuitry for varying characteristics of stimulation applied, such as amplitude, pulse width, rate and burst, selectable by key card, program, radio controlled or manual switch or other control means. The stimulator may be pre-programmed with a plurality of programs which are

selectable by the patient or clinician. Individual combination settings may be selected from any of program cards which include multiple combinations by switch operation, which switch may be on the stimulator or on the card. Miniaturized stimulators may be implanted within a human body. The stimulator may include a fault alarm and/or an audio analyzer, which emits sound to simulate the amplitude, rate and pulse width being delivered by the stimulator.

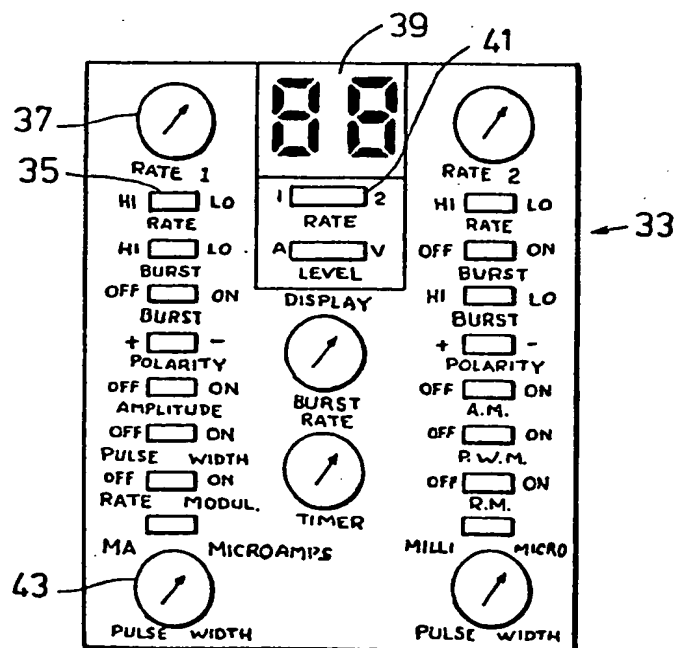


FIG. 6

FIG. 1

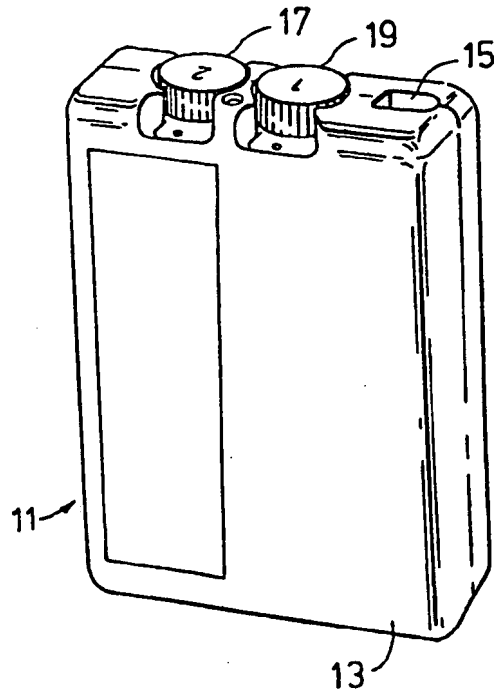


FIG. 2

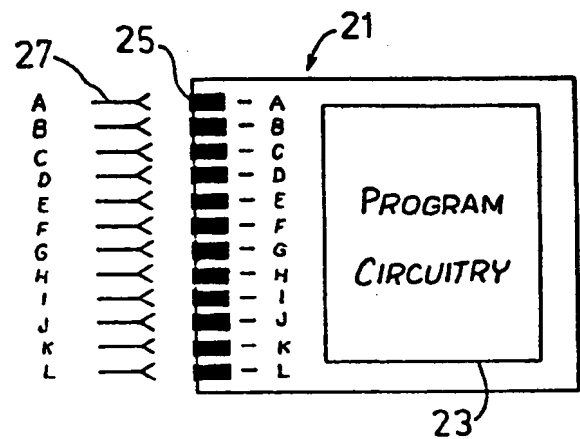


FIG. 6

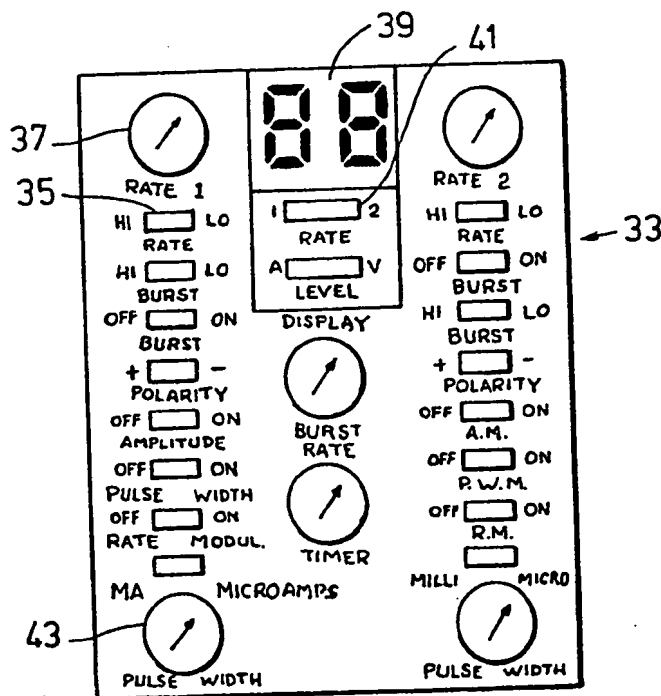
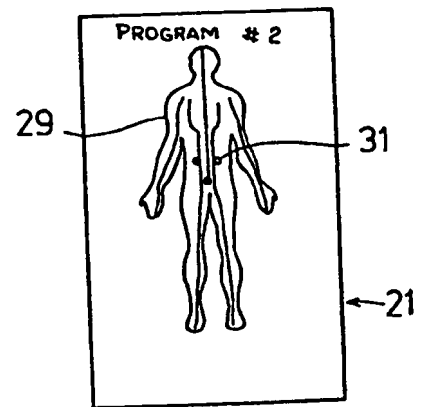
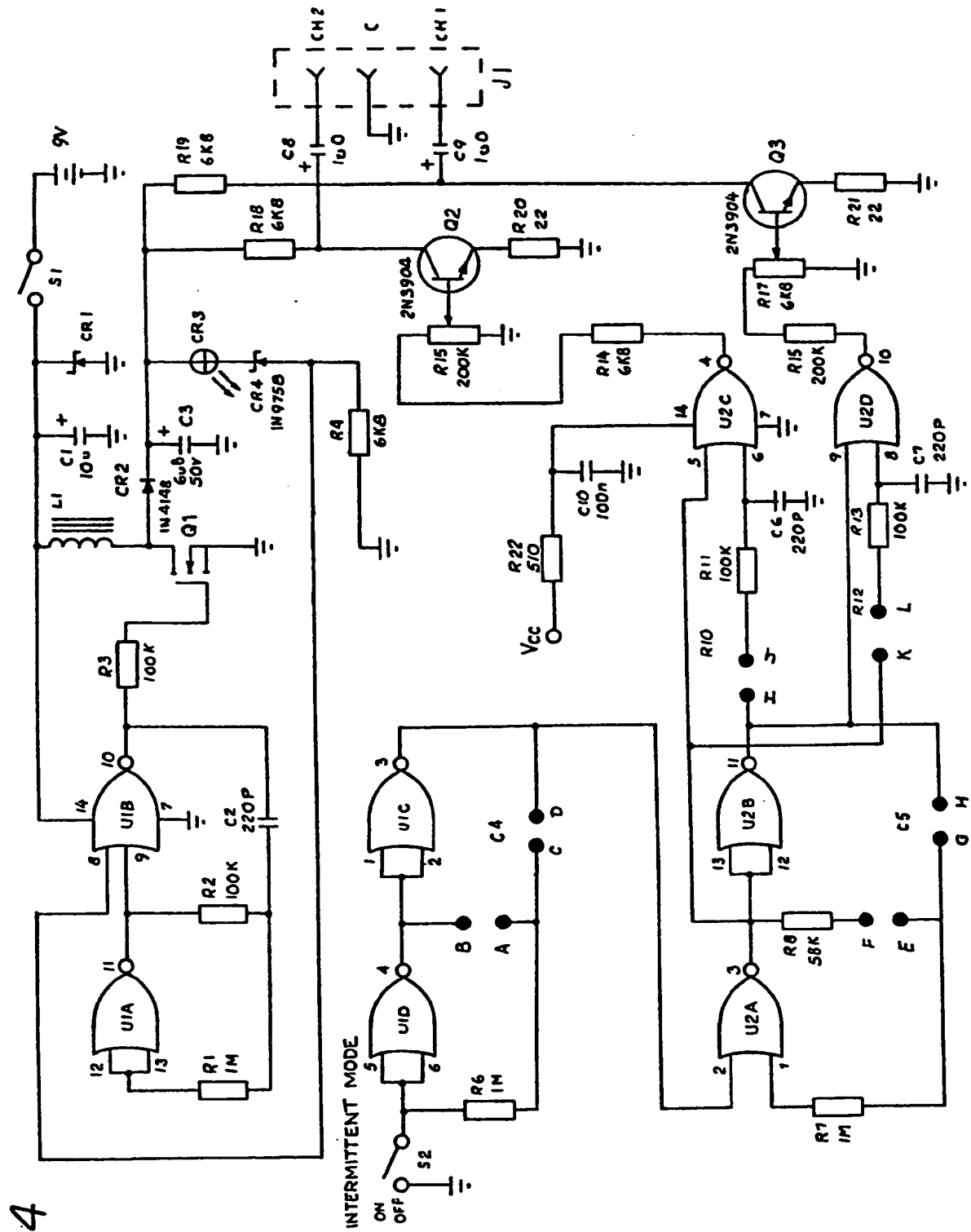
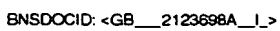


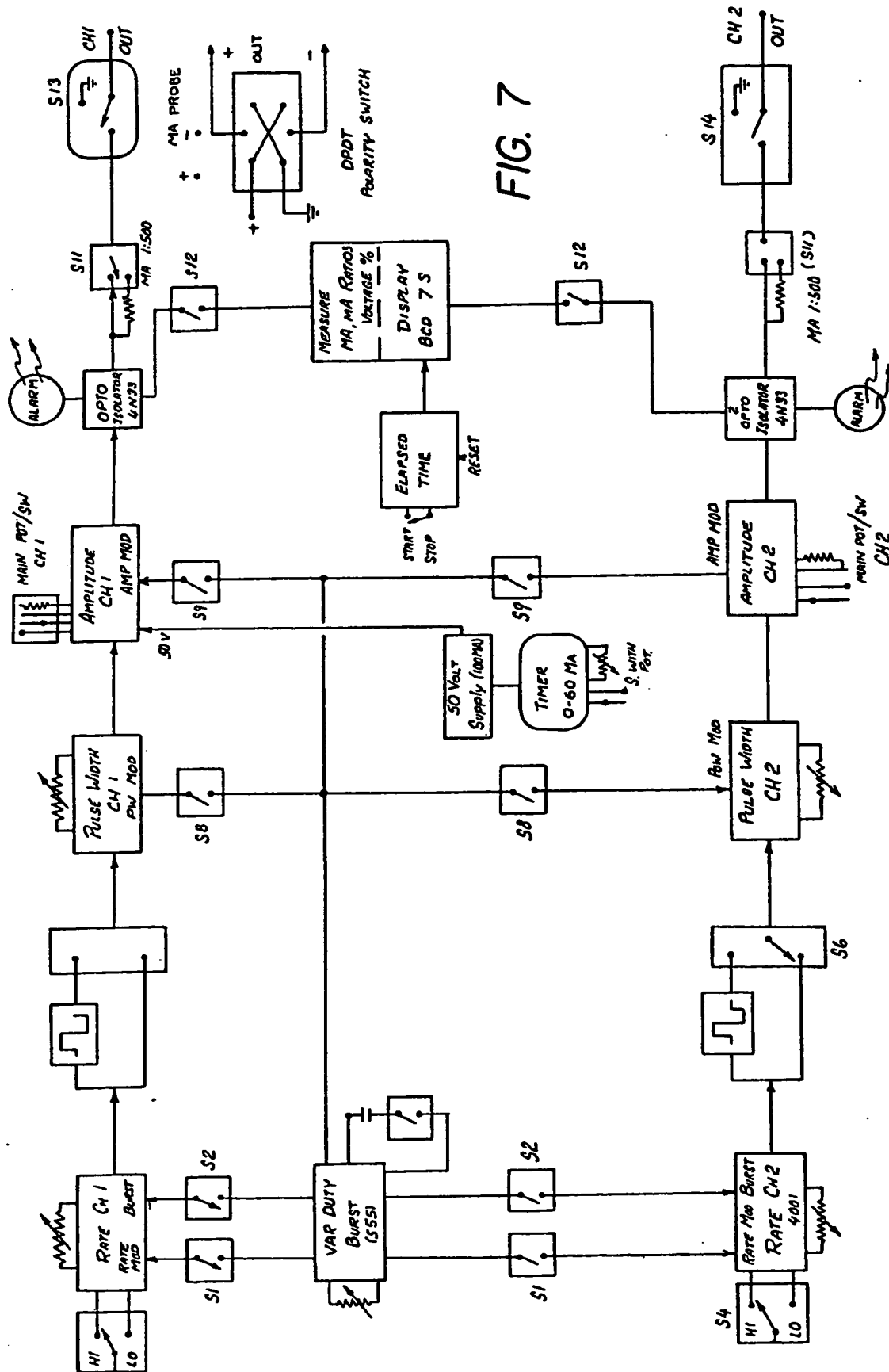
FIG. 3





INTERMITTENT MODE





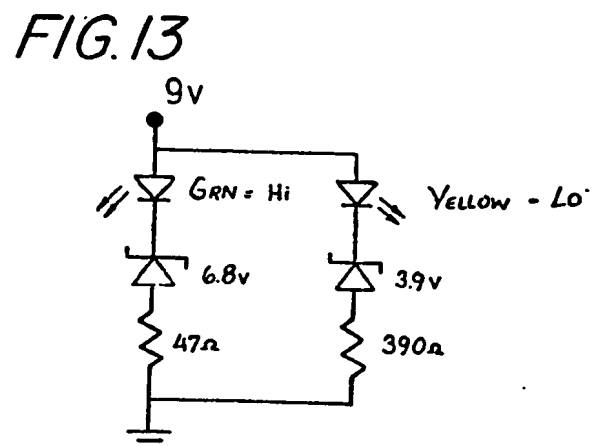
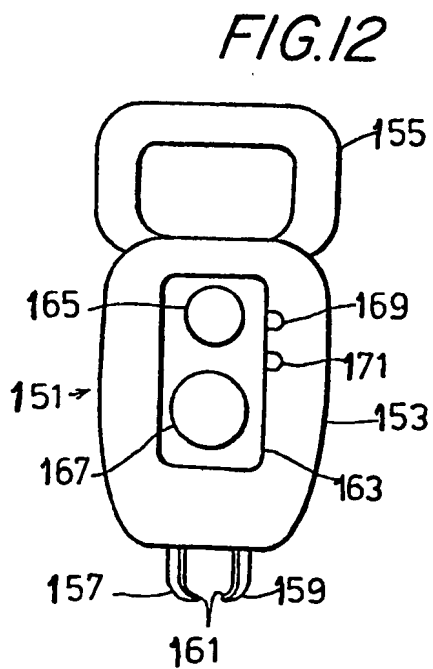
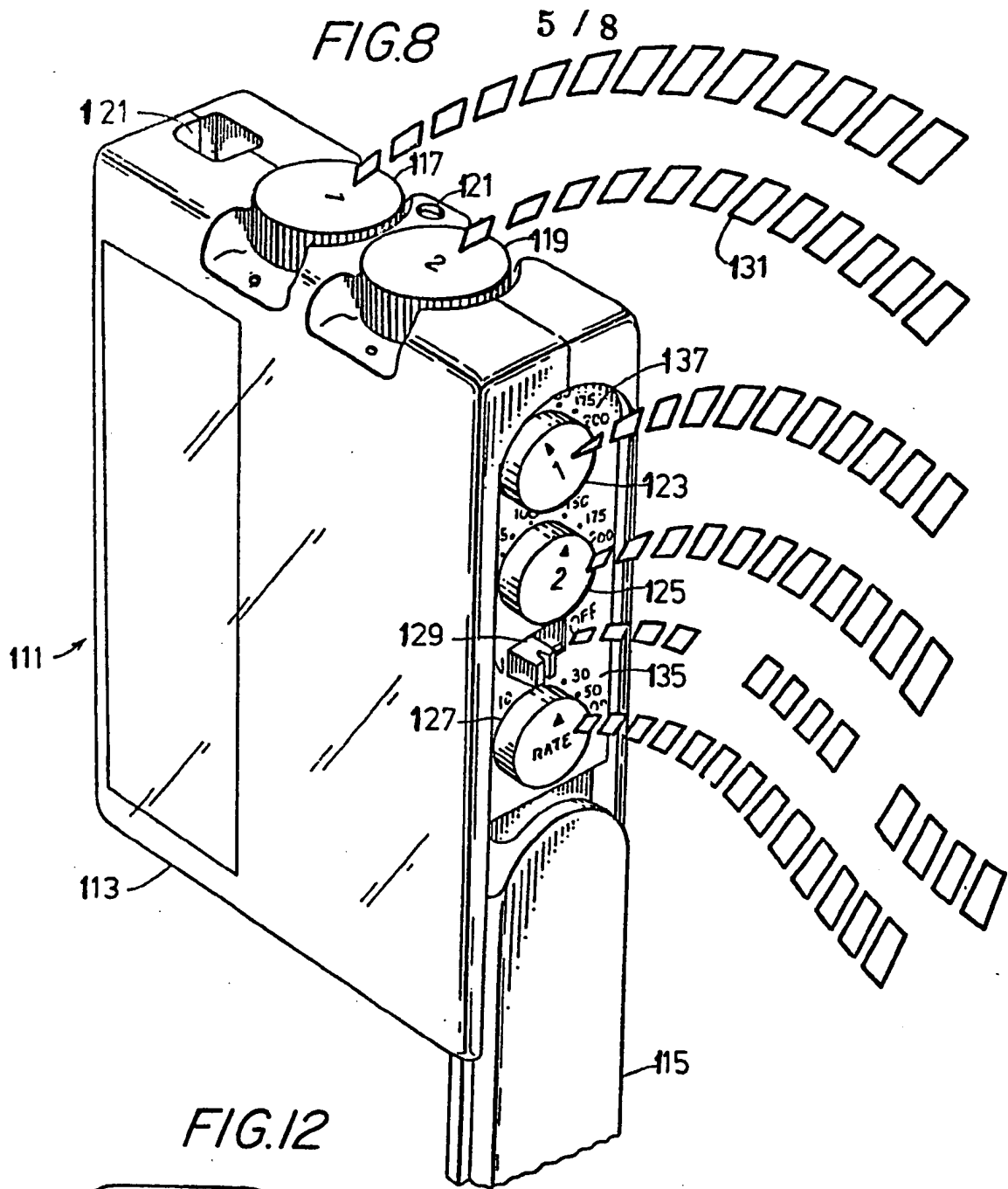


FIG. 9

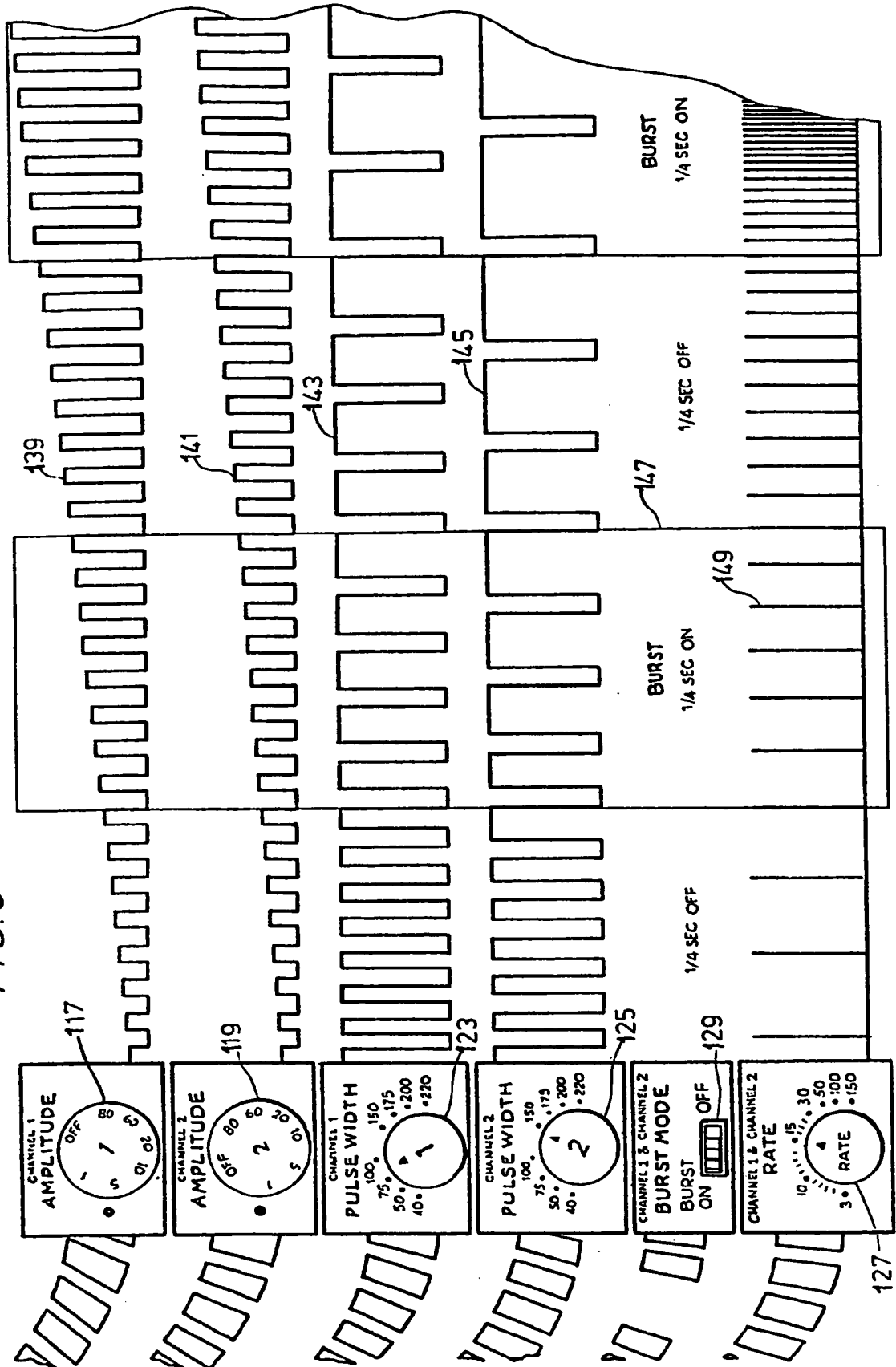


FIG. 10

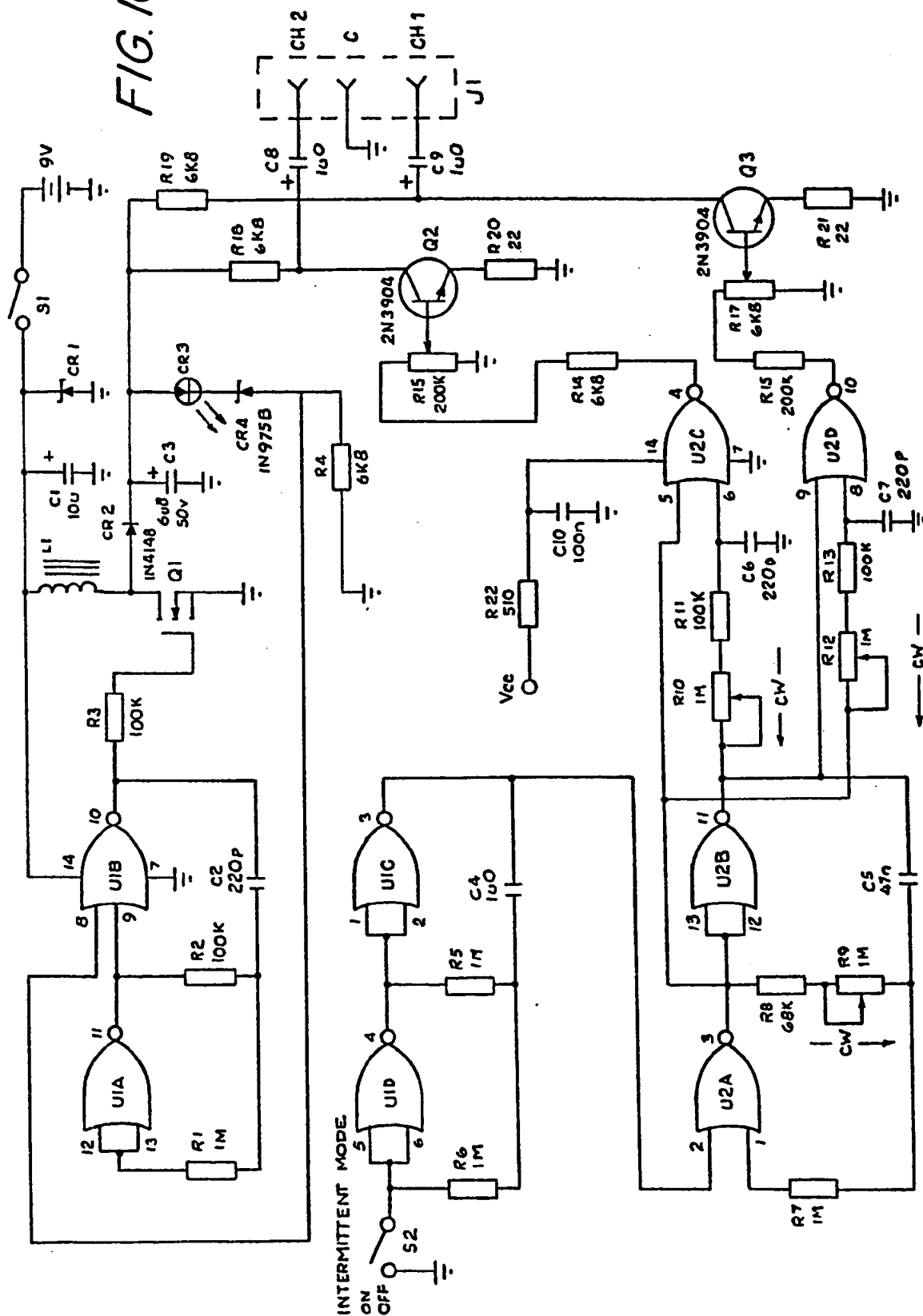
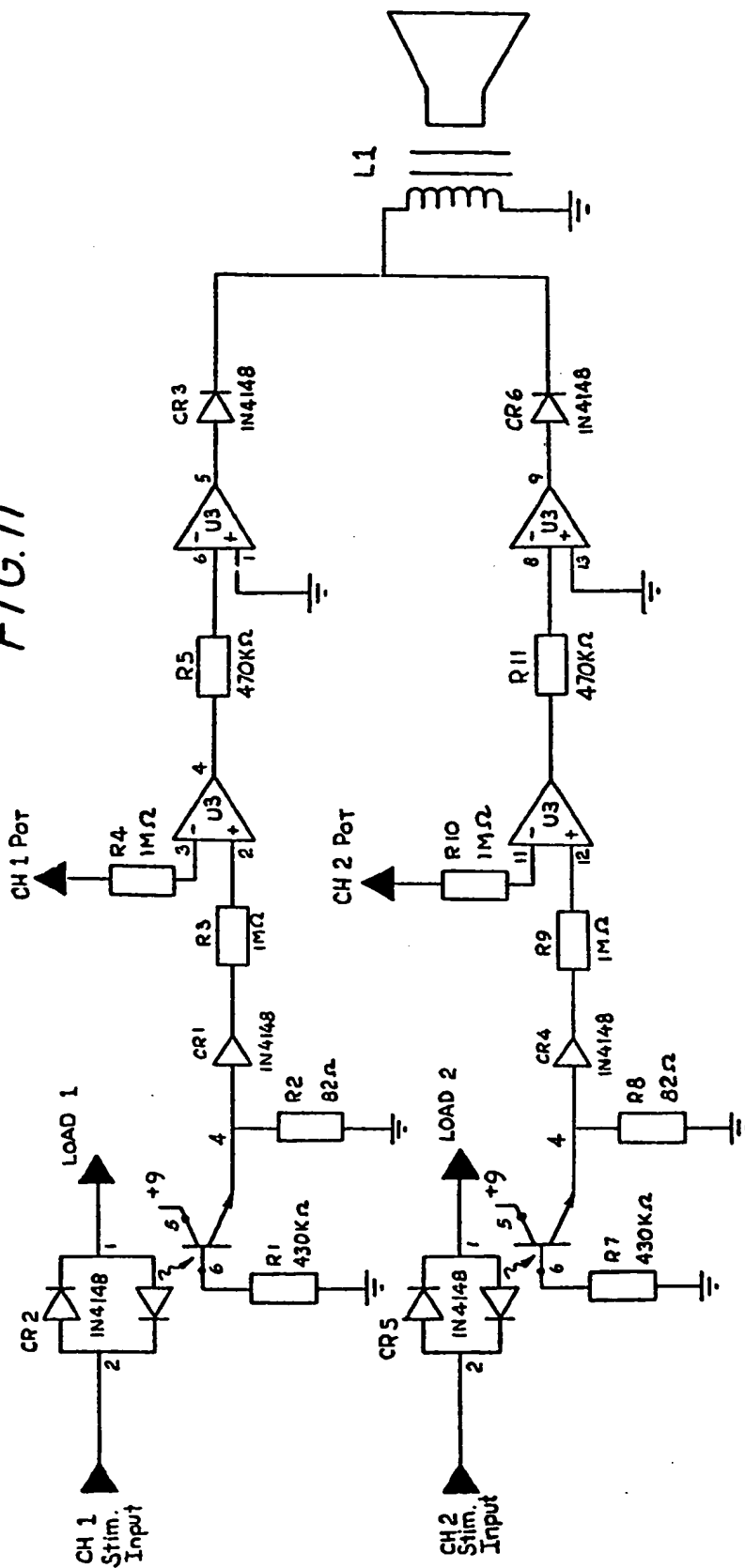


FIG. II



U1, U2 - 4N33 Optocoupler
 U3 - LM3900 Quad Op-Amps
 L1 - Audio Buzzer

SPECIFICATION

Biological electrical stimulators

This application relates to biological electrical stimulators, such as transcutaneous electrical nerve stimulators, useful in alleviating human pain, although the invention should not be considered to be limited to T.E.N.S. devices.

Biological electrical stimulators have been manufactured and sold and presently are being prescribed by various doctors for the relief of human pain. They may also be employed for treating animals, such as race horses, and other living organisms. In addition to pain relief, such stimulation may have various other desirable effects on an organism, such as: promoting circulation; assisting in the determination of the condition and responsiveness of various body parts; stimulating bone growth; increasing blood circulation; exercising muscles; and aiding in medical research.

It is an object of the present invention to provide improved biological electrical stimulators that are versatile, safe, attractive, easy to employ and trouble-free.

In accordance with the present invention a biological electrical stimulator, adapted, when powered by a suitable battery and connected via electrical leads and electrodes to a plurality of locations on a living organism, to electrically stimulate such organism, comprises electrical circuitry for varying the characteristics of the electrical stimulation applied to the organism in response to any of a plurality of programs which can affect such circuitry to vary the characteristics of the stimulation. Such programmable stimulators are actuable by any of different program cards which are insertable in the stimulator to make contact with contacts thereof so as to program the stimulator for desired operation. Such programs may be capable of setting the stimulator to operate in conventional, acupuncture-like, pulse-train or brief-intense modes, either for a single channel or for a plurality of channels and may intentionally apply only to some parameters so that others may be manually or otherwise non-programmably controllable. In addition to the mode control, the programs may also control amplitude, pulse width, rate, burst and other characteristics of the stimulator, and may modulate one or more of amplitude, pulse width and rate for one or more channels. In some instances it may be desirable to utilize program control for selecting low, medium, high or ultra-high frequencies and in other cases the program may modify the stimulator to operate in the milliamperage or microampere range.

Also described herein are improved stimulators, which include audio alert features and audio analyzer features. Furthermore, to assist in checking the conditions of batteries employed in the biological electrical stimulators an improved battery tester is disclosed.

A further development of the programmable stimulator of this invention which will be evident

to one of skill in the art from the drawing and this description is that wherein the stimulator carries in the circuitry thereof a plurality, and preferably a multiplicity of programs, sometimes amounting to more than a hundred, with numbers from 10 to 150 and more or less being practicable. The specific operation of the stimulator is selectable by use of a keycard, program, radio frequency-controlled switching mechanism, manual switch, electronic control or other means so that the desired operation of the stimulator can be obtained and so that the characteristics of the electrical stimulation may be selected for most effective treatment of a certain type of pain in a certain location on a patient of a certain weight range. It is contemplated that program cards for the operation of those programmable circuits for which they are suitable may be created in sets, with each card bearing the code to set the stimulator for treatment of a certain type of pain, or for a plurality of types of pains. When a card bears plural codes the stimulator may have an additional selecting mechanism, such as a mechanical switch, for blocking out some of the card signals so that only one treatment is signalled per channel at a time. Of course, when the present devices are miniaturized and made impenetrable to body fluids they may be implanted in the human body or in an animal so that parts thereof may continuously, or intermittently on command, alleviate chronic or acute pain.

Another improvement over other biological stimulators is in increased versatility of the stimulator, which includes a plurality of channels with independent amplitude, pulse width and rate controls so that multi-modal stimulation is obtainable. Stimulators of this type may have amplitude controls which are independently variable over about the 0—80 ampere range, pulse width controls which are independently variable over about the 20 to 300 microsecond range and independent pulse rates which allow for selective utilization of different frequencies for each channel, said frequencies being in the range of about 2 to 10 kilohertz. Also, a burst mode that is adjustable over a period of about 0.2 to 4 seconds is provided and either or both of an audio analyzer to simulate stimulation, and an audible fault alarm may be included.

Biological electrical stimulators are usually intended for use by the patient according to previous instructions given to him by a doctor, physiotherapist or other health professional. In such cases the patient may not have to know the various characteristics of the stimulation. However, for clinical use it is often desirable to be able to read directly the various parameters of amplitude, pulse width and frequency, rather than to rely on a knob or dial setting. Also, for clinical use various other operations are often desirable, as the clinician attempts to alleviate the patient's pain to the greatest extent. Therefore, in what may herein sometimes be termed a clinical biological electrical stimulator, independent plural channels are provided and means are provided for varying

the stimulation characteristics of each channel with respect to amplitude, pulse rate and burst, continuously over ranges for each such parameter. Preferred clinical stimulators include: a polarity

- 5 reversal switch; outlet levels in the milliampere and microampere ranges, means for producing uniphasic and biphasic wave shapes selectively, means for modulating stimulation characteristics, usually within the range of 10 to 90%, e.g., 40 to
- 10 90%, thereof; visual read-outs of amplitude, pulse width, rate and burst for a plurality of channels, which read-outs may be by means of L.E.D.'s. or liquid crystals, a shut-off timer, an elapsed time indicator, a ramp feature so that amplitude may be
- 15 gradually increasable to desired maxima during stimulations, an audio alert feature; an audio analyzer feature; and a hand holdable probe which can also function as a point stimulator.

- 20 The invention will be readily understood by reference to the specification, taken in conjunction with the drawing, in which:

FIG. 1 is a perspective view, on a slightly reduced scale, of a transcutaneous electrical nerve stimulator of a type of this invention;

- 25 FIG. 2 is an enlarged rear elevational view of a program card of this invention;

FIG. 3 is a front elevational view of the card of FIG. 2, rotated 90°;

- 30 FIG. 4 is a circuit diagram of the stimulator of FIG. 1;

FIG. 5 is a circuit diagram of another embodiment of the invention;

- 35 FIG. 6 is a front elevational view of a clinical stimulator, showing a wide variety of changeable parameters and modes obtainable with it;

FIG. 7 is a circuit diagram of such clinical stimulator, including reversing means and probe attachment means;

- 40 FIG. 8 is an enlarged perspective view of a non-programmable biological electrical stimulator of the T.E.N.S. type with a cover thereof partially removed to expose normally hidden controls;

- 45 FIG. 9 is a simplified pictorial representation in chart form of the operation of the T.E.N.S. of FIG. 8, with broken lines connecting various controls and representations of FIG. 9 with similar broken lines shown in FIG. 8, so as better to relate the illustrations;

- 50 FIG. 10 is a circuit diagram of the T.E.N.S. of FIG. 8, omitting audio alert and audio analyzer signalling circuitry;

FIG. 11 is a circuit diagram of the audio signalling circuitry which is adapted for utilization with the circuitry of FIG. 10;

- 55 FIG. 12 is a bottom plan view of a battery tester of the invention; and

FIG. 13 is a circuit diagram of the test device of FIG. 12.

- 60 In FIG. 1 stimulator 11 includes a body portion 13 which contains a power source (battery), electrical circuitry, and means for insertion of a program card, such as is illustrated in Figs. 2 and 3, into correct electrical contact with portions of such circuitry. After insertion of the card, which is
- 65 insertable in the left side of the stimulator, as

shown, and making appropriate contacts, normally electrode leads are fastened to contacts from the stimulator at location 15. Adjustment knobs 17 and 19 are shown on the stimulator for regulating amplitude for two channels, so that stimuli may be applied to different body portions (or different stimuli could be applied to a single body portion). Thus, the patient still retains the capability of increasing or decreasing the stimulation level although otherwise the stimulator characteristics may be fixed.

- 70 In Fig. 2 program card 21 includes program circuitry 23 and contacts 25 (only the A contact being specifically designated herein). In Fig. 2 there are also shown leads from the internal circuitry of stimulator 11 which may be brought into contact with the program card leads. For example, when the program card is installed in the stimulator, contact 25 will be in good electrical
- 80 contact with lead 27, as will be the other lettered contacts and leads.

- 85 In Fig. 3, on the front of the program card 21 an illustration 29 of a human figure has indicated thereon, at locations like that identified as 31, positions for placement of electrodes or probes. Thus, for program No. 2, that illustrated in Figs. 2 and 3, three positions are shown, one of which is for a common ground. For stimulators having four electrodes an additional position for electrode
- 90 application may be illustrated.

- 95 FIG. 4 and the circuit diagrams of Figs. 5 and 7 are completely self-explanatory and need not be discussed further at length. However, it will be noted that in the circuit diagram of Fig. 4 contacts A—L, corresponding to those shown in Fig. 2, are indicated. Also, while Fig. 4 does not show the details of the audio alert and audio analyzer circuitry, such as shown in Fig. 11.

- 100 FIG. 5 illustrates the circuit diagram of another version of an improved stimulator of this invention, with various mode and parameter changes being effectable by operations of the various switches to affect stimulation parameters and characteristics. The circuitry shown in Fig. 5 may be included in a stimulator body like that illustrated in Fig. 1 or in other suitable variations thereof.

- 105 In Fig. 6 clinical stimulators 33 (or the control and operation panel thereof) is shown. Such is almost self-explanatory but some features thereof will be specially mentioned. It will be noted that the stimulator indicated is a two-channel device, with the right side of the panel duplicating the left side but applying to a second channel. Thus, referring to the left side, it will be noted that a switch 35 is provided for selecting either a high or low rate range and the setting of such range may be effected by movement of knob 37. Display 39 will show the actual rate when rate switch 41 is in appropriate position. Similarly, pulse width is controllable by setting knob 43. Other changes that are possible are in the presence or absence of burst, the selection of a positive or negative polarity, the selection of rate modulation and the employment of a timer. For some displays, as
- 110
- 115
- 120
- 125
- 130

on the read-out. Of course, the illustrated panel of a stimulator, while representative of a typical such panel of the clinical stimulator of this invention, 5 may be modified so as to include other adjustments and in some cases some of those shown, if not warranted, may be omitted. Nevertheless, it is considered that the illustration indicates the significant utility of this stimulator, 10 especially when equipped with a liquid crystal or other suitable visual read-out means so that a clinician may know exactly the characteristics of the stimulation being administered.

Like the other circuit diagrams, Fig. 7 is 15 considered to be self-explanatory to one of skill in this art. However, it is particularly noteworthy that the provision of a separate ground for the different channels has been found to result in greater independence of operations, which is often 20 important, especially for research stimulation. The diagram is representative of the described device and illustrates what is considered to be the best mode thereof but, like almost all electronic circuits, similar effects may be obtainable with 25 other combinations of components and these too are considered to be within the present invention insofar as such changes would be within the skill of an electronics specialist.

In Fig. 8 T.E.N.S. unit 111 comprises a casing 30 113 for the battery (which is not shown but is present under a portion of the cover), normally hidden controls, to be described, electrical circuitry (not shown) and sliding cover 115, which is removable for access to the hidden controls and 35 for insertion and removal of the battery. Knobs 117 and 119 are amplitude controls for individually adjusting the current flow to the electrodes of the two channels, which currents flow from contacts at location 121, through 40 conductive wires and electrodes to locations on the living organism (usually the human body) to be treated. Knob 123 is for control of the pulse width in channel 1 and knob 125 is similarly for control of the pulse width in channel 2. Knob 127 is for 45 control of rate or frequency, and for the unit illustrated it controls such rate for both channels. Switch 129 is for burst mode control and shows on-and-off positions only, with the burst for such unit being $\frac{1}{4}$ second on, followed by an off period 50 of $\frac{1}{4}$ second. Light 121 goes on when either or both of knobs 117 and 119 are turned on. Indicia 137 and 135 are present near the pulse width and rate knobs to indicate the actual pulse width in microseconds and the frequency in hertz. Similar 55 indicia on knobs 117 and 119 indicate the current flow in milliamperes. Diagrammatic connectors like that illustrated at 131 are shown to indicate relationships between parts in this figure and the same parts in Fig. 9.

In Fig. 9 amplitude knob 117 is shown and bars 139 are of varying heights, signifying increasing the current flow in the first channel as knob 117 is turned clockwise. Similarly, knob 119 is for changing the amplitude in the second channel and 65 numeral 141 indicates a lower current flow level

119 are turned on, and the contacts are connected to the stimulator and the contacts are good so that current flows satisfactorily to the organism being treated, initially an audio signal 70 will result, indicating that the battery is operative, but after the knob is rotated about 15° from the off position such signal will be terminated. However, when the battery is good but a contact between electrode and organism surface is 75 abnormally high the audio signal will be given initially and will remain on despite rotation of the adjusting knob. When the the battery is unsatisfactory there will be no signal at all and no current will flow to the subject. Numerals 123 and 80 125 indicate pulse width control knobs and different widths are shown in bars designated 143 and 145, with the latter of such bars indicating that the pulse width for the second channel is greater than that for the first channel. As is 85 indicated, as the control knob is turned clockwise the pulse width increases. Numeral 129 designates a burst on-off switch and numeral 147 identifies a burst mode. Numeral 127 identifies 90 the rate control knob and bars 149 represent rate of frequency. The distances between bars 149 are inversely proportional to the frequency and, as is shown, the frequency increases with clockwise turning of knob 127.

In Fig. 12 battery tester 151, in the form of a 95 keychain or key holder, includes a body portion 153 a key holding portion 155 and claws or grips 157 and 159 which have end surfaces 161 facing each other and useful for grasping stimulator 100 control knobs, especially the hidden control knobs which may be difficult for infirm patients or those with arthritic fingers to turn. Other designs for grips may also be employed, such as a socket wrench-like structure for fitting over the knobs 105 (with the knobs being fluted to be easily held). Body 153 includes a raised portion 163 thereon, in which there are recessed contacts 165 and 167, for the positive and negative terminals of a nine-volt battery. The electronic circuitry, shown in 110 Fig. 13 is embedded in section 163 and is of such type that when a fully charged battery has its terminals in contact with contacts 165 and 167 L.E.D. 169 will be illuminated (a green light). However, if the battery is not a new one or at its 115 full voltage output but is still operative, L.E.D. 171 will be lit, providing that the voltage of the battery is at least about 5. When the voltage is below 5 neither light will be lit. Thus, the battery tester is a handy article which is extremely useful for 120 operating the present biological electrical stimulator and checking the power source therefor.

The battery tester may also utilize a liquid crystal display instead of the L.E.D's., so that the battery voltage may be read directly, and the 125 tester body portion may be made to simulate or resemble the stimulator body in appearance and finish, so as to suggest the stimulator to a user.

Some additional aspects of the various 130 embodiments of the invention will now be

discussed, together with advantages resulting from the invention. Overall, improved programming flexibilities of the stimulators, which are made possible by precision electronic circuitry and to some extent by accurately calibrated output controls, allow greatly improved controls of various stimulation parameters for most effective patient examination, treatment and research. Settings for best treatments may be recorded and may be referred to as guides to future treatments. Because of the independence of parameter adjustments and the capability of the units utilizing common or separate grounds, so that with two channels one may utilize either three or four electrodes, treatment may be of one section of the organism, crossed by both channels, or treatments of plural locations may be effected, and different stimuli may be applied, either to the same or different locations. When sequential stimulation is employed, wherein the current is applied to two channels at different times so that the effect thereof is not additive in "shocking" action, a more comfortable sensation is obtained and energy efficiency and battery life are improved.

With respect to the programmable stimulators, whether actuated by program cards, built-in microprocessors or combinations of programming and switching means, research has established the best treatment effects for various types of pain and for various modes of application, some of which are considered to be best for particular types of pain. Such treatments may be recorded in booklet form to assist doctors and therapists in prescribing most effective T.E.N.S. treatment for pain. It has been contemplated that over 100 programs could eventually be produced, based on such combinations of parameters and modes, and probably about 300 cards (three variations of each program) could be made so that any of the 100 programs could be selected for any of three body weights of a patient (thin, normal and heavy). The choice of three body weights seems sufficient to allow optimum stimulation, on the basis of experimental evidence, with greater levels of stimulation usually being required for heavier patients. For example, in a particular card or module, intended for bimodal stimulation employing ultrahigh frequency, burst mode and acupuncture-like stimulation parameters, the pulse rate in channel 1 could be ten kilohertz with that in channel 2 being two kilohertz, the pulse width in channel 1 could be 40 microseconds whereas in channel 2 it could be 20 microseconds, the amplitude may be 0 to 10 milliamperes in channel 1 and 0 to 8 milliamperes in channel 2 (regulatable within this range by the patient) and the burst can be 50 hertz in channel 1 with no burst in channel 2. It is a simple matter for these characteristics to be programmed into a program card or internal chip for use in an activatable programmed stimulator. The described module allows for the use of ultrahigh frequency channel 1 stimulation on the patient's head with simultaneous acupuncture-like (APL) stimulation

of the upper extremities. Such treatment provides for fast relief of headache pain with good carry-over. APL T.E.N.S. is not normally applied to the head because it is generally not well tolerated on the head or face.

The programmable stimulator is normally prescribed by the physician or therapist after evaluation of the patient's pain and condition. Thus, the clinician can give the patient a single card which pre-sets the stimulator into the desired mode of operation, thereby preventing accidental changing of the parameters. If it is desired that the patient be allowed to apply a plurality of parameters such is possible by issuing him several cards or by having the information on a single card, with selector switches on the stimulator. Similarly, when a pre-programmed stimulator is employed, means for actuating the proper program will be supplied to the patient and all other programs will normally be blocked out by the clinician before release of the stimulator to the patient.

The programmable T.E.N.S. operates in conventional mode, acupuncture-like mode, pulse-train mode, brief-intense mode and in a multi-modal manner. In the multi-modal manner each channel can be programmed to function in a different mode. In the various modules burst modulation can be programmed to function at a predetermined frequency within the 0.4 to 3.5 hertz range, one channel can be programmed to function at a predetermined frequency within the 0.5 to 20 kilohertz range, the unit can be programmed automatically to modulate amplitude, pulse rate and/or pulse width parameters and one or both channels can be programmed so that an amplitude in the microampere range (as well as the milliampere range) can be utilized. Microampere range stimulation may be desirable with point probes or in special situations.

Among the advantages of the programmable T.E.N.S. is that it helps to eliminate any confusion on the part of the patient regarding operation of the unit, it allows patients with arthritic hands and fingers to utilize the stimulator because only the amplitude control needs to be adjusted (and in some cases such may be pre-set by means of the program card), and the patient can easily remove and insert one or more program cards to set the unit into its mode (or modes) of operation. In cases where different stimulations are desirable for morning and evening application, two program cards may be supplied, appropriately marked, and similar plural cards may be utilized for use at home and at work. Also, when the pain is variable, different program cards may be supplied which are suitable for each type of pain.

The non-programmable stimulator includes a choice of pre-set pulse rates in the low, conventional and ultrahigh frequency ranges which are independent of channels. Among the benefits of this specific feature are the availability of multi-modal stimulation, which allows for simultaneous utilization of different stimulation

5 modes in the plural channels, so that a patient
with two related or unrelated areas of pain may
benefit from the use of such separate stimulations.
The ultrahigh frequency feature, when utilized at
5 low amperage and narrow pulse duration, allows
for stimulation that is tolerated while on the head
and thus helps to make the T.E.N.S. effective for
headache treatment. The capability of changing
stimulation modes by means of pulse rate
10 switches allows for each changing from
conventional to acupuncture-like treatment, which
is often desirable after fast pain relief is obtained
with the conventional mode. The switch to a low
rate (2 hertz) with a corresponding increase of
15 amplitude and pulse duration can also provide
for a long-term carry-over of relief. Occasionally
such a change in the stimulation mode should be
accompanied by a corresponding change in
electrode placement. When one changes from
20 ultrahigh frequency to conventional or
acupuncture-like mode (such changing procedure
may often be followed because while ultrahigh
frequency treatment may be useful for fast pain
relief it should not be used for long periods of
25 time) one may step down to conventional and
then to acupuncture-like modes for the remainder
of the stimulation and such changes aid in
producing prolonged relief.

The clinical/research unit is suitable for treating
30 patients but is primarily designed for clinical
experimentation and patient evaluation. The
doctor or therapist, using this stimulator, can thus
determine the optimum stimulation mode or
modes, parameters, modulation, etc., which
35 provide the greatest degree of benefit to each
individual patient. Also, due to the great versatility
of this stimulator highly individualized programs
for each patient can be determined and a suitable
program for use with a programmable stimulator
40 of this invention may be selected or may be
created according to prescription. The stimulation
parameters are variable so that an infinite number
of pain control formulas may be applied. While
there are limits on the various parameters, the
45 presences of high and low ranges and the
continuous variability obtainable provide a wide
range of stimulation parameters. The
independence of the channels is important
because the therapist may evaluate the effects of
50 each specific channel, especially when used at
two different areas of the body, and there is no
need to compromise a treatment of one body area
because another area is also being treated and the
channels are interrelated. The visual read-outs of
55 stimulation parameters allow the therapist to
depend on such readings and not have to be
guided by nominal dial settings, which sometimes
can be inaccurate. The pulse rate range is
individually adjustable over a conventional range
60 of from about 1 to 150 hertz and the ultrahigh
frequency range previously mentioned. The burst
modulation provides for low frequency, pulse-train
modulation of the stimulation mode, which is
often highly desirable. It also allows for milder
65 stimulation treatments and battery life is

increased when burst is utilized. The wide range of
burst modulation available will help to improve the
effectiveness of T.E.N.S. treatments. Of course,
this is also so because of the availability of wide
70 ranges of the other parameters of the electrical
stimulation, too.

The availability of the microampere range
switch for one or both channels so that the
stimulation can be within about the 0 to
75 400 microampere range allows for research and
treatments with small oral and facial electrodes,
such as may be employed during dental
procedures. The availability of the ramp feature
permits a gradual increase in stimulation to the
80 maximum setting (over 0.5 to 10 seconds).
Because of this feature one may obtain muscle
contraction, which is sometimes desired, with
increased comfort and better patient tolerance to
the stronger stimulation modes. The wave form,
85 which may be changed between asymmetrical
and symmetrical biphasic wave forms, allows for
the effectiveness of each form to be determined
and, if desired, each channel can produce a
different wave form. The timer feature, including
90 elapsed time and time limit features, allows the
therapist to check the time needed for pain relief
and also to limit the period of stimulation
application during treatment (and prevent
overlong treatment of the stimulator, the doctor
95 can actually listen to the stimulation
characteristics as the patient describes the effects
thereof. The employment of the Zener regulation
circuit, which limits outputs to a desired voltage,
e.g., 40 volts, as the absolute maximum, reduces
100 wild voltage excursions such as could otherwise
occur with load fluctuations due to improper
electrode connections. Thus, if one electrode is
removed or loses adherence during treatment
there will not be a surge of current to the other
105 electrode or stimulation channel and shocking of
the patient will be avoided.

While it is more usual to utilize either one or
two channels, with two, three or four electrodes,
additional electrodes can be connected to the
mentioned channels, if desirable, or additional
110 channels may be employed. Thus, 5 to 8 or more
electrodes may be used. In the described
stimulators the burst mode can be switched on or
off at any time during stimulation without having
to turn the entire stimulator off. In the illustrated
stimulator the burst mode is limited to $\frac{1}{4}$ second
115 on and off but the amplitude, rate and pulse width
can be varied over fairly wide ranges, from about 1
to 80 milliamperes, 3 to 150 hz., and about 40 to
120 220 microseconds, and such adjustments may be
effected while the unit is in burst mode or in
standard mode. Furthermore, by adjustment of
circuitry and/or electrodes, other variations of
these modes may also be obtainable, such as
125 those which are designated as acupuncture-like or
brief-intense.

While it is contemplated that the described
stimulator will be worn in a clothing pocket or on a
patient's belt (and the stimulator includes a
130 mounting clip, not shown in the drawing) it is also

within the invention to miniaturize the stimulator so that it may be worn concealed, under the patient's clothing. Such miniaturization has been effected to the point where the unit is now less than 20% of its original approximately 125 cubic centimeter volume. When the full size unit is worn on a belt it is preferred that it be mounted on a swivelling belt clip which allows the patient to swivel the unit for easy adjustments of parameters without removing it from the belt.

The present stimulators are essentially trouble-free, largely due to the advanced integrated circuit design. The stimulator is operated by a single disposable or rechargeable nine-volt battery which has a comparatively long treatment life. Thus, for a setting at 25 milliamperes, 75 microseconds and 80 hz., battery life will normally be 135 hours of use when a single channel is employed and 75 hours for dual channel application. Utilization of the burst mode extends the life of the battery to 325 hours (single channel) or 225 hours (dual channels).

The employment of the present power supply circuit allows a reduction in size of the stimulator, compared to circuits employing one or more transformers, because the transformers must be of a much higher capacity. For example, the present inductor may be of a rating of about 3 to 7% of that of a comparable transformer. The oscillator of the present system may develop a frequency in the range of about 1 to 16 kilohertz and the battery voltage may be increased from one in the range of about 5 to 9.3 volts, to one in the range of 40 to 60 volts, usually about 40 volts. Similarly, the Zener regulation circuit will regulate such voltage to be within such range or possibly within the slightly broader range of about 30 to 60 volts.

While it is preferred that the casing for the present stimulator be a precision machined metal casing, such as one of stainless steel, with a precision fitted slide in a side thereof to permit access to hidden controls and the battery, it is within the invention to utilize other materials for the case, such as synthetic organic polymeric plastics and other metals, e.g., aluminum. Also, while the illustrated control types and locations are preferred, these may be varied to suit the circumstances.

The described stimulators have been tested on humans for relieving various types of pain, including lower back pain, arthritic pain, trauma pain, "tennis elbow" pain and neuralgic pain and it has been found that when they are employed at the prescription of a doctor and under his direction, statistically significant and often sensational effects in pain relief result. In some cases patients previously rendered immobile by pain have become ambulatory and can function nearly normally.

The invention has been described with respect to various illustrations and embodiments thereof but is not to be limited to these because it is evident that one of skill in the art with the present specification before him, will be able to utilize substitutes and equivalents without departing

from the invention.

CLAIMS

1. A biological electrical stimulator, adapted, when powered by a suitable battery and connected via electrical leads and electrodes to a plurality of locations on a living organism, to electrically stimulate such organism, which comprises electrical circuitry for varying the characteristics of the electrical stimulation applied to the organism in response to any of a plurality of programs or actuatable circuits which can affect or alter the stimulator circuitry to vary the characteristics of the stimulation.

2. A stimulator according to claim 1, for use on animals and human beings, wherein different program "cards" are insertable in the stimulator to make contact with contacts thereof so as to program the stimulator for desired operation.

3. A stimulator according to claim 2 for transcutaneous electrical nerve stimulation of humans wherein the insertable programs are for one or more of the following modes: conventional; acupuncture-like; pulse-train; brief-intense.

4. A stimulator according to claim 1 wherein the different electrical circuits for varying the stimulation are settable, selectable or actuatable by a doctor or user thereof.

5. A stimulator according to claim 3 which includes a plurality of channels, at least one of which is programmable.

6. A stimulator according to claim 1 wherein amplitude (current) is non-programmably controllable.

7. A stimulator according to claim 1, for transcutaneous electrical nerve stimulation of humans wherein the insertable programs or actuatable circuits control one or more of the following stimulator characteristics: amplitude; pulse width; rate; burst.

8. A stimulator according to claim 7 wherein one or more of amplitude, pulse width and rate are programmably modulated.

9. A stimulator according to claim 7 wherein the rate is programmably modifiable to ultra-high frequency.

10. A stimulator according to claim 7 wherein the amplitude is programmably modifiable to microampere range.

11. A biological electrical stimulator, adapted, when powered by a suitable battery and connected via electrical leads and electrodes to a plurality of locations on a living organism, to electrically stimulate such organism, which comprises electrical circuitry for varying the characteristics of the electrical stimulation applied to the organism in response to any of a plurality of actuatable programs or circuits incorporated in the stimulator, which programs or circuits are selectively actuatable to affect such circuitry to vary the characteristics of the electrical stimulation.

12. A stimulator according to claim 4 including means responsive to externally imposed force or energy to select a particular program or circuit and

stimulator administers electrical stimulation of desired characteristics.

5 13. A stimulator according to claim 12 wherein a plurality of channels for electrical stimulation is present and each is programmably controllable by application of external force or energy.

10 14. A program card for controlling the circuit characteristics of a biological electrical stimulator and thereby controlling the electrical stimulation applied to an organism to which the stimulator is connected which comprises a card body, electrical circuitry in the body, connectible by contact members of the card with fitting contact members of the stimulator to vary electrical characteristics of the stimulator and thereby control one or more of the following stimulator characteristics: amplitude; pulse width; rate; and burst; in at least one of the following modes: conventional, acupuncture-like; pulse-train; and brief-intense.

20 15. A stimulator according to claim 1 which is implantable within a human being.

25 16. A stimulator according to claim 5 which comprises visual read-outs of amplitude, pulse-width, rate and burst for the plurality of channels.

30 17. A biological electrical stimulator, adapted, when powered by a suitable battery and connected via electrical leads and electrodes to a plurality of locations on a living organism, to electrically stimulate such organism, which comprises an audio alert feature which causes emission of sound when a fault condition, including improper attachment of electrodes, broken wires to the electrodes, or disconnected

18. A stimulator according to claim 17 wherein sound is emitted when the stimulator is turned on, to indicate that the battery is providing power, sound emission ceases when amplitude adjustment is made and current flows to the organism through normal electrode contacts and through normal means connecting the stimulator to the electrodes, and sound emission continues when such normal flow of electricity is not obtained.

45 19. A stimulator according to claim 17 wherein the audio alert feature circuitry includes an optical coupler for non-invasively operating sound emitting means when an abnormally high impedance in the energy supply circuit to the organism is detected.

50 20. A biological electrical stimulator, adapted, when powered by a suitable battery and connected via electrical leads and electrodes to a plurality of locations on a living organism, to electrically stimulate such organism, which comprises power supply circuitry for increasing the battery voltage to a desired voltage for application to an organism which includes an audio analyzer feature which causes emission of sound to simulate the amplitude, rate and pulse width being delivered by the stimulator.

60 21. A battery tester which comprises contacts adapted for contact with battery terminals and electric circuitry adapted to light a plurality of light emitting diodes when the battery is fully charged and to light a lesser number or none of such diodes when it is less fully charged.